

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL  
COMPANY, INC., et al.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS,  
INC., et al.,

Defendants.

Civil Action No. 3:09-cv-5421 (GEB)  
(TJB)

**Date Returnable: September 7, 2010**

**Filed Electronically**

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**DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S REPLY  
BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT**

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### **Preliminary Statement**

Mutual's Opposition Brief affirms what West-Ward contends: there are no genuine issues of material fact such that judgment to West-Ward is warranted as a matter of law. There is only one fact that is essential to resolution of this case: whether Mutual engaged previously in the same conduct that it now attacks. Mutual's submissions affirm that this is the case. The rest is of no moment.

Mutual has admitted, as it must, that for more than a decade, it did precisely what it disparages now: it sold unapproved colchicine tablets in the same fashion via the same Price Lists and Wholesaler Ordering Systems that it faults West-Ward for using. Likewise, it sold its unapproved colchicine wrapped in the very same package inserts that West-Ward still uses. Ironically, West-Ward and co-Defendant Excellium manufactured much, if not all, of the product that Mutual sold.

In the face of these facts, Mutual cannot credibly argue that its conduct was not the same as West-Ward's. Thus, in order to avoid the unclean hands doctrine, it is relegated to maintaining that after thirteen years of unapproved colchicine sales, it heeded the FDA's call to seek regulatory approval and ceased committing the sorts of supposedly "willful" and "illegal" acts that it attacks West-Ward for in this case. In sum, Mutual now asks this Court to turn a blind eye to its identical past conduct.

As the following discussion will show, Mutual cannot escape the consequences of its prior actions by donning a white hat and claiming that it is the “good guy” that was just following a new FDA directive. In point of fact, Mutual’s motive for seeking FDA approval was not altruism, not the public interest and not safety, but money; and the law regarding FDA approval is far from new. Again, however, these facts are immaterial. It does not matter why Mutual sought FDA approval. The only fact that matters here is that Mutual’s previous sales of unapproved colchicine – the very thing of which it now complains – bar its continued prosecution of this case.

#### **I. MUTUAL EXAGGERATES THE ELEMENTS OF THE UNCLEAN HANDS DEFENSE.**

Contrary to Mutual’s assertions, federal courts do not hesitate to apply the unclean hands doctrine in a proper case. Mutual’s reliance on the strict five-element analysis set out in outdated and non-binding decisions such as *Castle v. Cohen*, 676 F. Supp. 620, 627 (E.D. Pa. 1987) and *Pfizer, Inc. v. International Rectifier Corp.*, 538 F.2d 180 (8th Cir. 1976), is misplaced. Both the Supreme Court and the Third Circuit identify “the critical element,” *New Valley Corp. v. Corp. Property Assoc. 2 & 3*, 181 F. 3d 517 (3d Cir. 1999) (citing *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 250 (1933)), of the unclean hands doctrine to be whether there is an “immediate and necessary relationship,” *id.*, between both parties’ conduct. Because Mutual engaged in the *precise* conduct

that it now alleges is “unlawful” and “willful,” the unclean hands doctrine mandates dismissal of Mutual’s claims.

A. Mutual Engaged In Conduct Identical To That Which It Now Contests.

In light of the “clear and convincing” evidence of the nexus between its conduct and West-Ward’s, it is fairly remarkable that Mutual contests this element of West-Ward’s case. Mutual expressly has *admitted* that:

- (1) for 13 years
- (2) it sold unapproved colchicine tablets
- (3) using the exact same product inserts and dosing instructions as West-Ward
- (4) by listing the same information for its unapproved colchicine – such as product name, strength, package size, label and insert, NDC number and pricing – on the same Wholesaler Ordering Systems and Price Lists as West-Ward and
- (5) denoting its unapproved colchicine as NR for “Not Rated,” just like West-Ward’s.

Mutual’s Response to West-Ward’s Statement of Undisputed Material Facts (“RSOF”) at ¶¶ 12-14, 16, 19, 20. In fact, despite Mutual’s claim that it asked to be removed from certain Price Lists and Wholesaler Ordering Systems, the evidence is undisputed that Mutual’s unapproved tablets remained on both until at least 2009. Of course, these are the precise actions that Mutual now contends constitute false advertising in violation of the Lanham Act, thereby rendering

incomprehensible Mutual's assertion that there is not a "very close nexus" between its conduct and West-Ward's.<sup>1</sup>

Mutual's attempt to differentiate its sales of unapproved colchicine from West-Ward's because: (1) there was no FDA approved colchicine during the time of the bulk of its unapproved colchicine sales and; (2) the FDA had not yet issued its "directive" that firms seek approval, misses the mark on both counts. First, Mutual seeks to excuse its sale of over 100 million unapproved colchicine tablets because at the time it engaged in the very same conduct it now derides, all colchicine was unapproved. In other words, Mutual asks this Court to ignore its past behavior simply because everyone else was doing the same thing at the time. Either the conduct of all the unapproved colchicine sellers (including Mutual) was wrongful both then and now, and Mutual's past wrongdoing prevents further process of this litigation, or no one's conduct was wrongful and Mutual's claim fails nonetheless. Mutual cannot have it both ways: if West-Ward's current

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<sup>1</sup> While Mutual disagrees that it benefitted from sales of its unapproved product after 2006, this factual dispute is immaterial in light of the undisputed evidence that Mutual sold unapproved colchicine for more than a decade prior to 2006. There is no need to determine whether Mutual benefitted from the post-2006 sales nor is there any need to conduct further discovery regarding them. Mutual's request for additional discovery prior to the adjudication of this Motion should be denied. Because the *material* facts are admitted, there is no need to waste resources on immaterial discovery. See West-Ward's Response in Opposition to Mutual's Rule 56(f) Request for Additional Discovery, filed contemporaneously herewith.

conduct is illegal, as Mutual contends, it goes without saying that Mutual's prior sales of unapproved tablets were illegal as well.<sup>2</sup>

Next, contrary to Mutual's assertions, *see* Mutual Brief at 14, the FDA's 2006 Compliance Policy Guide ("CPG")<sup>3</sup> was not the "directive" that Mutual insinuates it was, nor did it impact the legality of Mutual's previous unapproved tablet sales. In the first instance, the CPG did not impose some new or different requirement. Rather, for the last forty-plus years, the FDCA has required all "new" drugs that are neither GRACE nor grandfathered to receive FDA approval. *See* 21 U.S.C. 355. Because that statute came on the books almost fifty years ago, it is disingenuous of Mutual to pretend that the CPG changed the face of the law.

Nor is the CPG binding in any way. Not only does it explicitly state that it "does not operate to bind FDA or the public," CPG at 1, every page disclaims that it merely "***Contains Nonbinding Recommendations.***" *See* CPG. Thus, to the extent that the sale of unapproved colchicine is "unlawful," as Mutual alleges, such sales did not become *more* unlawful upon publication of the CPG. Stated

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<sup>2</sup> As noted in the Declaration of Michael Raya accompanying West-Ward's opening brief, West-Ward maintains that its colchicine tablets are "grandfathered drugs," as opposed to "new" drugs, and thus do not require approval under of 21 U.S.C. § 355(a). Resolution of this issue is within the primary jurisdiction of the FDA and, thus, outside of the scope of this case.

<sup>3</sup> The CPG is Exhibit A to the Declaration of Nishan Kottahachchi.



differently, the FDA's release of the CPG did not transform Mutual's conduct into something entirely distinct from West-Ward's, as Mutual suggests.

Likewise, Mutual's insistence that the CPG was some sort of enforcement "directive" is belied by the fact that, despite Mutual's having constantly bombarded the FDA with written pleas to force all unapproved colchicine off the market, FDA steadfastly has refused to act against West-Ward.<sup>4</sup> Considering that the FDA has not decreed that West-Ward's continued sales of unapproved colchicine tablets are problematic, Mutual certainly is not in position to advocate such a conclusion to this Court.

Mutual's related position that its decision to stop selling unapproved colchicine cleanses its unclean hands is similarly flawed. As the court in the Lanham Act case of *Proctor & Gamble Co. v. Ultreo*, 574 F. Supp. 2d 339 (S.D.N.Y. 2008), aptly explained when it applied the unclean hands doctrine to Proctor & Gamble ("P&G"), "at a time when P&G's commercial interests were different, P&G made the very same claims that it now attacks as false, and relied on the very science it now claims is inadequate." *Id.* at 355.

Similarly, in *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510 (S.D.N.Y. 2009), the court barred Stokely Van Camp ("SVC") from pursuing its

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<sup>4</sup> See RSOF at ¶¶ 30, 42 and 50. Mutual cites three warning letters that the FDA issued to other manufacturers, but those letters demonstrate nothing more than that FDA has some enforcement discretion in this arena; they do not prove that West-Ward's product is not grandfathered, and have no bearing on this case.

false advertising claim against Coke because it previously had engaged in the very same conduct. Because there, SVC, like Coke, touted the advantages of adding magnesium and calcium to its sports drink, the court concluded that "SVC cannot, having jumped on the bandwagon of calcium and magnesium first, now jump off and claim that Coca-Cola must get off too." *Id.* at 534.

A case from this circuit reached a similar result. In *Salomon Smith Barney, Inc. v. Vockel*, 137 F. Supp. 2d 599, 603 (E.D. Pa. 2000), the court denied Smith Barney relief because it previously had engaged in the same conduct: "If what Vockel is doing in 2000 is wrong, it is hard to see why Vockel's and Smith Barney's conduct in 1994 was not wrong." *Id.* at 603. *See also West v. West*, 825 F. Supp. 1033, 1050 (N.D. Ga. 1992) (holding that the unclean hands doctrine was designed to stop a plaintiff from "seeking to stop essentially the same types of transactions from which he once benefited"). In like manner, if what West-Ward is doing in 2010 is wrong, Mutual's identical conduct from 1993 to 2006 was as well. Just because Mutual chose to change its business model, it cannot now demand that West-Ward do the same.

Mutual's abject inability to offer any response to these cases speaks legions. Its silence affirms that equity will not allow it to sell unapproved colchicine when

it is convenient, stop when it is lucrative, and then sue West-Ward for continuing to sell the same unapproved drug.<sup>5</sup>

Finally, Mutual summarily concludes that its sales of unapproved colchicine “could not have contributed to any consumer confusion regarding the safety and efficacy of colchicine products.” Mutual Brief at 3. Mutual proceeds to fault West-Ward for failing to present any evidence to the contrary in support of its unclean hands defense. Mutual’s argument is nonsensical and attempts to place a burden on West-Ward that does not exist. To be clear, Mutual’s lawsuit is premised on the allegations that the existence of unapproved colchicine tablets on Wholesaler Ordering Systems and Price Lists deceives consumers into believing that those tablets are FDA approved. Complaint at ¶ 18. It is unreasonable for Mutual to argue that this alleged confusion miraculously arose on the exact date that Mutual obtained FDA approval for its tablets. To the extent that consumers

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<sup>5</sup> This brief assumes for the sake of argument that the mere listing of a product on a website can state a claim for false advertising under the Lanham Act. West-Ward disagrees with this contention because the Lanham Act addresses “false advertising,” and not mere “selling.” Should this case progress, West-Ward will file a summary judgment motion directed to this and other issues. Mutual’s argument that West-Ward should not be allowed to file a subsequent motion ignores the fact that both judicial economy and this Court’s rules compel the assertion of the unclean hands defense at this time. *See* Fed. R. Civ. P. 1 and the Chamber’s Procedures of the Honorable Garrett Brown, Jr. (“resolution of disputes is best achieved when issues are identified and addressed early in litigation.”)

are confused by the marketing of unapproved colchicine, as Mutual contends, it goes without saying that Mutual's prior conduct contributed to such confusion.<sup>6</sup>

B. Mutual's Conduct Is Sufficiently Willful To Support Application Of The Unclean Hands Defense.

Selectively relying on two Pennsylvania district court cases, Mutual contends that West-Ward must show that Mutual engaged in "egregious misconduct" in order to support an unclean hands defense. Mutual Brief at 12-13. Both this Court and the Third Circuit disagree. In fact, in this circuit, in order to invoke the unclean hands doctrine, the proponent need show only "[a]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct ...." *Saudi Basic Indus. Corp. v. ExxonMobil Corp.*, 401 F. Supp. 2d 383 (D.N.J. 2005) (quoting *Monsanto Co. v. Rohm & Haas Co.*, 456 F. 2d 592, 598 (3d Cir. 1972)). Anyone "who consciously ignores the obvious risks associated with an action and who performs the act regardless is acting willfully." *Id.* at 396.

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<sup>6</sup> The Complaint also alleges that West-Ward's package inserts gives rise to a false advertising claim. Not only did Mutual use the exact same package inserts as West-Ward, RSOF at ¶ 16, but courts consistently reject the view that safety and efficacy information on a drug's package insert can support a false advertising claim. See *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F. 2d 222, 231-32 (3d Cir. 1990); *Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008).

Ironically, Mutual's own Complaint amply evidences that Mutual's conduct was willful. It specifically alleges that *West-Ward's* marketing of colchicine tablets without FDA approval is "willful," based simply on the contention that West-Ward's sales of unapproved colchicine are illegal. Complaint at ¶¶ 146, 163. Of course, that is precisely what Mutual did: it sold unapproved colchicine under the exact same statutory framework upon which it now relies. Hence, if West-Ward's conduct is willful, Mutual's must have been as well. Thus, Mutual's conduct amply satisfies the willfulness element.

C. Harm To West-Ward Is Not An Element Of The Unclean Hands Defense.

Espousing another legal error, Mutual firmly states that "[u]nder well-established law in this District and the Third Circuit, to establish a defense of unclean hands, West-Ward must show that it was injured as a result of Mutual's alleged misconduct." Mutual Brief at 21. In actuality, the Third Circuit has expressly rejected Mutual's statement of the law. As early as 1959, the Third Circuit adopted the view that a "defendant who invokes [the unclean hands doctrine] need not be damaged," *Gaudiosi v. Mellon*, 269 F. 2d 873, 882 (3d Cir. 1959) (citations. omitted), and forty years later reaffirmed that point. *See New Valley Corp. v. Corp. Prop. Assoc. 2 & 3*, 181 F. 3d 517, 526 (3d Cir. 1999) (to apply the clean hands doctrine, "no injury need[] be shown"). This Court has confirmed that principle as well. *See Saudi Basic Indus. Corp. v. ExxonMobil*

*Corp.*, 401 F. Supp. 2d 383, 392-93 (D.N.J. 2005). Accordingly, whether or not Mutual's conduct caused West-Ward harm is immaterial to this case.

D. The Public Interest Weighs In Favor Of Applying The Unclean Hands Doctrine To Bar Mutual's Pursuit Of These Claims.

Mutual makes a two-part public policy argument. First, despite the fact that colchicine has been used for over a century and at no time has the FDA taken any enforcement action against West-Ward, Mutual classifies West-Ward's unapproved colchicine as "dangerous" and "potentially fatal." Next, Mutual opines that a dismissal of its claims on the basis of its unclean hands would cut against the FDA's nonbinding policies with respect to unapproved drugs. These arguments have no merit.

As a threshold matter, it is important to remember that this is a false advertising lawsuit; not an FDA enforcement action. Mutual is seeking to use the Lanham Act to do that which the FDA has not. That is, because the FDA has refused to compel the removal of West-Ward's colchicine from the market, Mutual seeks to do it for the agency in the guise of a civil suit. That is not the purpose of the Lanham Act, nor can the Lanham Act support such a result.

Next, Mutual disingenuously claims that being held accountable for its prior "bad" acts would "create a disincentive for pharmaceutical companies to undergo the expensive and time-consuming FDA approval process ...." Mutual Brief at 1. Of course, this is not so. No matter the outcome of this Lanham Act case, Mutual

reaps the benefit of being able to claim that it is the only FDA-approved colchicine on the market. Moreover, had it not engaged in the same conduct itself that it now attacks, (and assuming that West-Ward actually had engaged in false advertising, which it has not), Mutual would not be plagued by unclean hands. It has only itself to blame. Because it engaged in the very conduct that it now contests, equity bars its claim.

Finally, contrary to Mutual's view, public policy actually favors West-Ward's continued sale of its product. The Court cannot overlook the fact that Mutual increased its price 5000% after it secured FDA approval. RSOF at ¶ 34. Thus, the public outcry related to this case, including a front page article in the Wall Street Journal, has not been focused on alleged safety concerns with a drug that has been sold for over 100 years, but rather on Mutual's monopolistic prices that limit accessibility to patients. *See* Declaration of Jared M. Lina, filed contemporaneously with West-Ward's Brief in Support of its Motion for Summary Judgment, at Tabs 27-32. Accordingly, the public interest actually weighs in favor of applying the unclean hands doctrine to dismiss Mutual claims.

## **II. THE CASE LAW AMPLY SUPPORTS A GRANT OF SUMMARY JUDGMENT TO WEST-WARD BASED ON MUTUAL'S UNCLEAR HANDS.**

Mutual levies a two-fold attack on West-Ward's case law, neither arm of which has merit. First, it claims that West-Ward relies on preliminary injunction,

not summary judgment cases. Second, it purportedly distinguishes West-Ward's cases as involving situations in which the conduct at issue was "substantially identical." It is fairly obvious that each contention suffers from legal or factual errors.

First, from a legal standpoint, while not always the case, the procedural posture of the unclean hands decisions is fairly immaterial to their resolution. While courts utilize varying standards in ruling on different motions, the principles underlying the unclean hands doctrine are well-established and consistent no matter what phase the litigation may be in. The principle that equity will not permit a party to sue another for doing what it used to do applies universally to all phases of the litigation process.

Moreover, as a factual matter, Mutual's contention fails in any event. Certain of West-Ward's cases arose in the summary judgment context. *See, e.g., Rainbow Play Sys., Inc. v. Backyard Adventure, Inc.*, No. Civ. 06-4166, 2009 WL 3150984 (D.S.D. Sept. 28, 2009); *Emco, Inc. v. Obst*, 2004 WL 1737355 (C.D. Cal. July 29, 2004). Thus, this first argument fails as a matter of both fact and law.

Mutual's second argument suffers a similar fate. While it does not deny its behavior, it refuses to acknowledge the fact that until 2006, it engaged in conduct identical to that which it now contests. As noted above, the simple fact that it chose to obtain FDA approval does not change the past. That Mutual decided to



seize the opportunity to attempt to reap monopoly profits by securing FDA approval does not somehow vitiate more than a decade of unapproved colchicine sales. Accordingly, Mutual's past conduct was not merely substantially, but absolutely, identical to that of which it now complains thereby warranting a grant of summary judgment in this case.

### **III. THE UNCLEAN HANDS DOCTRINE BARS BOTH MUTUAL'S EQUITABLE AND MONEY DAMAGE CLAIMS.**

Mutual contends that even if the unclean hands doctrine bars the equitable relief that it seeks, the doctrine "is an equitable defense that cannot bar Mutual's remedies at law." Mutual Brief at 28. Once again, Mutual's legal analysis is faulty. The Lanham Act expressly provides that recovery of any profits or money damages are "*subject to the principles of equity.*" 15 U.S.C. §1117(a) (emphasis added). *See TrafficSchool.com, Inc. v. Edriver, Inc.*, 633 F. Supp. 2d 1063, 1087 (C.D. Cal. 2008) ("[a]s an equitable remedy, disgorgement of profits is particularly susceptible to the affirmative defenses of unclean hands and laches."); *see also Rainbow Play Sys., Inc. v. Backyard Adventure, Inc.*, 2009 WL 3150984 (D.S.D. Sept. 28, 2009) (a Lanham Act damage award is "subject to the principles of equity"); *George Basch Co. v. Blue Coral, Inc.*, 968 F. 2d 1532, 1540-41 (2d Cir. 1992) (every Lanham Act award is "subject to equitable principles"). Accordingly, Mutual's unclean hands bar all the relief that it seeks and a grant of summary

judgment to West-Ward on all of Mutual's claims, both monetary and equitable, is warranted in this case.

### **Conclusion**

Based on the foregoing and West-Ward's opening submissions, West-Ward's Motion for Summary Judgment (Docket No. 265) should be granted.

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